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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,399	12/21/2001	Brian J. Martinell	38-21(51470)	2956
27161	7590	11/19/2004	EXAMINER	
MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: G.P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,399

Applicant(s)

MARTINELL ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 28 June 2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, filed 30 August 2004. Applicant elects Group I, (Claims 1-19), drawn to a method early identification of germline transformed plants comprising transforming tissue with at least one nucleic acid sequence encoding a protein to obtain transformed plant tissue, with traverse. Applicant traverses, stating they believe that it would not create an undue burden on the Examiner to conduct a search encompassing all of the claims. Applicant traversal is unpersuasive. Applicant gives no reason to support their belief.

2. Claims 1-21 are pending. Claims 1-19 are examined in this action. Claims 20 and 21 are withdrawn as being drawn to non-elected inventions. This restriction is made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, filed 28 June 2002 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 16 –19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, (d) line 10, "the shoots" lacks antecedent basis.

Correction/ clarification are required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11, 13-14 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6, 384,301 (hereafter '301).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application

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and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Applicant claims a method of early identification of germline transformed plants comprising steps of: (a) transforming meristematic or cotyledonary tissue with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein to obtain transformed plant tissue; (b) producing a shoot from the transformed plant tissue; (c) growing roots from the shoot; (d) assaying the roots for the presence of the nucleic acid sequence and (e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants. Dependent claims are drawn the method wherein the plant expressible construct encodes a protein conferring a trait to the plant, the plant expressible construct comprises at least two nucleic acid sequences, wherein the roots are grown in the presence of a selection agent; wherein the selection agent is kanamycin; wherein the selection agent is glyphosate; wherein the transformation is via *Agrobacterium* mediated transformation or particle mediated transformation; wherein the plant is a dicot plant; a soybean plant, or a cotton plant.

Further claims are drawn to a method of obtaining of germline transformed plant cells via kanamycin selection comprising steps of: (a) providing a heterologous DNA comprising a promoter functional in plants transforming meristematic or cotyledonary tissue with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein to

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obtain transformed plant tissue; (b) inserting a DNA construct into the meristematic tissue of a plant embryo; producing a shoot from the transformed plant tissue; (c) inducing shoot formation from the treated meristematic tissue by culturing on a culture medium; (d) culturing the shoots on a suitable shooting media containing kanamycin at a concentration sufficient to significantly inhibition the growth of untransformed plant cells to generate kanamycin resistant shoots; (e) regenerate the shoot of step (d) into genetically transformed plants having increased tolerance to kanamycin relative to wild-type plants; assaying the roots form the plants of step (e) for the presence of the DNA construct; and identifying roots that assay positive for the DNA construct as putative germline transformed plants.

US 6,384,301 teaches a method of identification of germline transformed soybean (claims 13 and 14) cells and plants comprising steps of: (a) transforming meristematic tissue(column 7, lines 24-25) with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein (column 7, lines 30) to obtain transformed plant tissue; (b) producing a shoot (column 7, lines 43-49) from the transformed plant tissue; (c) growing roots from the shoot (column 7, lines 43-49); (d) assaying the roots for the presence of the nucleic acid sequence (claims 5, 6, and 7) (column 4, lines 60-63 and column 5, lines 23-28) and (e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants (column 4, lines 60-63 and column 5, lines 23-28). Dependent claims are drawn the method

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wherein the plant expressible construct encodes a protein conferring a trait to the plant, the plant expressible construct comprises at least two nucleic acid sequence, wherein the roots are grown in the presence of a selection agent; wherein the selection agent is kanamycin; wherein the selection agent is glyphosate; wherein the transformation is via Agrobacterium mediated transformation or particle mediated transformation; wherein the plant is a dicot plant; a soybean plant, or a cotton plant.

Soybean is a dicot plant (claim 13 and 14). Glyphosate is an herbicide (claim 2). The language "assaying the roots for the presence of the nucleic acid sequence" is interpreted to encompass growing the roots in the presence of the selective agent, kanamycin or glyphosate.

The transformation method used is Agrobacterium mediated transformation (column 5, lines 18-41) (claim 8).

Accordingly, '301 anticipates the claimed invention

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,384,301 as applied to claims 1-11, 13-14 and 16-19 above, in view of applicant's admitted prior art, and further in view of US 5,994,624.

US 6,384,301 does not teach the use of PCR, RT-PCR or Southern blot to assay the roots from the shoots (claim 12) and does not teach transformation of cotton (claim 15)..

However, US 6,384,301 does teach the use of PCR of leaf tissue of R1 plants (column 8, lines 56-58) for confirmation of the germline transformation.

US 5,994,624 teaches the germline transformation of cotton (Example I, column 10, line 15-column 12, line 3).

It would have been obvious to one of skill in the art, at the time of the invention was made, to use the PCR assay of applicant's admitted prior art in the transformation method of the '301 patent and to substitute the cotton transformation of US 5,994,624 for the soybean transformation of '301, as PCT assays have been shown to function well in the confirmation of the presence of specific nucleic acid sequences in transgenic plant tissue and cotton is known to be germline transformable by Agrobacterium plant transformation. One skilled in the art would have been motivated to so, with a reasonable expectation of success, especially in the absence of evidence to the contrary, given the suggestion by US 5,994,624 and the success of US 6,384,301.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

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Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-9 and 13-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13 of U.S. Patent No. 6,384,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claims of patent 6,384,301 renders the genus claims of the instant application obvious.

This is a provisional obviousness-type double patenting rejection.

Remarks

10. Claims 1-19 are not allowed in view of the prior art. Any inquiry concerning this communication or earlier communications from the examiner

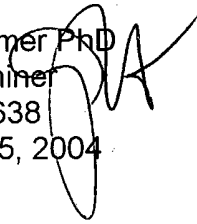
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should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Group 1638
November 15, 2004




ELIZABETH MCELWAIN
PRIMARY EXAMINER